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| 10/762,964 | 01/22/2004 | Kevin Tait | SW-045AX | 6339 |

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| EXAMINER | |
|---|---|
| SCHLIENTZ, LEAH H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/762,964 | TAIT, KEVIN | |
| | Examiner | Art Unit | |
| | Leah Schlientz | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-18 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/800,076.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1/22/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Double Patenting*

Claims 1 – 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 19 of U.S. Patent No. 6,726,896. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the similar stool marker formulations comprising barium sulfate and a flocculant. Accordingly, the scope of the pending claims overlaps with that of the patented claims, and thus they are obvious variants of the patented claims.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of claim 1 wherein 0.25 g of solid stool marker formulation is diluted with water to 50 mL does not appear in the disclosure as originally filed. Rather, the specification indicates that 2.5 g of powder is diluted to 50 mL with water (see footnote to Table 1, page 7). This is a new matter rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Note: Concerning the following rejections over prior art, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The recitation of "A stool marker", etc. is an "intended use" recitation which does not patentably distinguish. Further, "product-by-process" claims (e.g. prepared by sonification, etc.) are interpreted as relating to the product, see *In re Thorpe*, 777 F.2d 695, 698, 277 USPQ 964, 966 (Fed Cir. 1985). The claims have been examined with respect to the product, i.e. barium sulfate and a flocculant, with optional components in the dependent claims.

Claims 1 – 4, 6 – 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (US 3,236,735).

Brown discloses a contrast agent comprising barium sulfate and bentonite, which is known by those of ordinary skill in the art to be within the smectite clay mineral group (i.e. a flocculant and an anti-caking agent) (column 4, lines 50 – 67). The formulation may be in solid form, as it was noted that a dry composition containing both the barium

sulfate and additives is particularly convenient and economical to store and ship (column 2, lines 57 – 59). The formulation also includes a viscosity modifier, i.e. sodium carboxymethylcellulose (column 1, lines 45 – 55). It is noted that the claims are drawn to a solid formulation comprising barium sulfate and a flocculant. There are no limitations on the amounts of barium sulfate and flocculant in the instantly claimed solid formulation, and limitation that "if said formulation is diluted to provide 0.5 to 3% barium sulfate, etc." would inherently pertain to any solid formulation comprising an amount of barium sulfate and a flocculant that is capable of being diluted. Also, since the claims are drawn to compositions and not methods, there is no administered dose, and the compositions disclosed by the prior art would be capable of providing the doses as claimed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 4, 6 – 8, and 10 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 3,236,735) in view of Queuille (US 4,120,946).

Brown discloses solid contrast agents comprising barium sulfate and bentonite, which is known by those of ordinary skill in the art to be within the smectite clay mineral group (i.e. a flocculant and an anti-caking agent) (column 4, lines 50 – 67). The formulation may be in solid form, as it was noted that a dry composition containing both the barium sulfate and additives is particularly convenient and economical to store and ship (column 2, lines 57 – 59). The formulation also includes a viscosity modifier, i.e. sodium carboxymethylcellulose (column 1, lines 45 – 55). The compositions may include sorbitol, i.e. a sweetener or flavoring agent. See Example 3. The composition of Brown may be diluted with water and is orally administered and is useful for the detection of polyps via x-ray imaging, where CT and helical scanning are well known in the art to be common means of obtaining such x-ray images (column 5, lines 32 – 39).

Brown fails to teach a composition having the same concentrations of such components as claimed, and does not include xanthan gum in the formulation.

Queuille discloses a contrast agent comprising colloidal barium sulfate, and teaches that xanthan (Kelzan) is a well-known viscosity modifier that may be used as an equivalent to other viscosity modifiers and in various amounts (column 2, lines 45+). The compositions may also contain a citrate (i.e. citric acid).

It would have been obvious to one of ordinary skill to combine the x-ray contrast agent compositions disclosed by Brown comprising barium sulfate, bentonite (i.e. a smectite clay), and a viscosity modifier with those of Queuille, which comprise barium sulfate, xanthan gum, and a citrate, to prepare a contrast agent comprising barium sulfate, xanthan gum, smectite clay, and sodium citrate. For example, it would have been obvious to modify the composition of Queuille to include bentonite (i.e. a smectite clay) where a flocculant was desirable because Brown specifically teaches that bentonite increases flocculation of barium sulfate in the intestine (column 4, line 57). Furthermore, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... "[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

One of ordinary skill would have been motivated to optimize the concentrations of the components in the disclosed x-ray contrast agents to improve their effectiveness and / or safety. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Claims 1 – 10 and 12 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 3,236,735) in view of Ruddy (US 5,466,440) in further view of Weaver (US 3,935,0990).

Brown discloses solid contrast agents comprising particulate barium sulfate and a smectite clay and their administration for the detection of polyps via x-ray imaging, as set forth above.

Brown does not specifically teach that the compositions are made via shear or sonification or that the particle size is specifically 3 microns.

Ruddy teaches barium sulfate compositions that also comprise a smectite clay (montmorillonite) which are in particle sizes which encompass those claimed, (column 5, lines 50+ and claim 1). Ruddy teaches the use of high shear provides the advantages of decreasing the processing time (column 12, lines 30+).

Ruddy fails to teach that the shear is created using sonification. However, sonification is known in the art of particle or colloid preparation, as taught by Weaver.

Weaver teaches that sonification is a known method for producing high shear and is equivalent to other techniques, such as colloid milling, etc. (column 14, lines 36+).

It would have been obvious to one of ordinary skill in the art to prepare the barium sulfate and smectite clay formulation disclosed by Brown by shear / sonification because these are well known methods for preparing such particles / colloids, including particles within the claimed size, which provide decreased processing time and are equivalent to other colloid processing techniques, as shown by Ruddy and Weaver.

Claims 1 – 4, 6 – 8, 10, and 12 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 3,236,735) in view of Kaufman (US 6,331,116).

Brown discloses solid contrast agents comprising particulate barium sulfate and a smectite clay and their administration for the detection of polyps via x-ray imaging, as set forth above.

Brown fails to teach the step of administering the barium sulfate formulation over 24 to 48 hours, and fails to specify that four doses should be administered.

Kaufman discloses methods of imaging the colon. The bowel is prepared prior to conducting CT imaging, and is intended to create a condition where residual stool and fluid remaining in the colon present different properties than that of the colon interior and wall. An exemplary bowel preparation operation includes ingesting three doses of a 2.1% barium sulfate suspension during the day prior to the CT scan (column 16, lines 37 – 65).

Kaufman fails to teach a barium sulfate formulation that also comprises a smectite clay.

It would have been obvious to one of ordinary skill in the art to administer the barium sulfate and smectite clay formulation taught by Brown in the manner of administering a barium sulfate suspension taught by Kaufman because Kaufman also teaches a barium sulfate containing contrast agent for imaging stool, and that the benefit of preparing the bowel in the stated manner obviates the need for conventional colonic washing protocols (column 16, line 65). Furthermore, it would have been obvious to modify the step of administering multiple doses from three to four doses as a

matter of routine experimentation in order to identify the dosage regimen with desirable effectiveness.

***Conclusions***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lhs

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